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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC.,

Defendant.

Case No. 2:22-CV-05326-RGK-MAR

PLAINTIFF SANDOZ INC.'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Filed Concurrently Herewith:
1) Statement of Genuine Disputes;
2) Decl. of Todd Benoff and Exhibits
3) [Proposed] Order

Date: June 26, 2023
Time: 9:00 a.m.
Place: Courtroom 850

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I. INTRODUCTION

With the launch of biosimilars to Neulasta®, Amgen's [redacted] was to protect its multi-billion-dollar bottom line from competition. Amgen worked to [redacted] to convince payors and prescribers that its Neulasta Onpro® product was superior to competing biosimilars, which are delivered only via pre-filled syringe ("PFS"). Amgen devised two objectively flawed "studies" that claimed to prove that Amgen's Neulasta® Onpro® was more effective than biosimilars—including Sandoz's Ziextenzo®—at treating febrile neutropenia. Those "studies" became the centerpiece of Amgen's false and misleading advertising campaign, which Amgen [redacted] And it worked: Amgen reaped massive profits and [redacted]

Amgen should be held accountable for its false and misleading advertising. Through its summary judgment motion, Amgen argues that Sandoz cannot prevail because Sandoz cannot prove it was harmed by Amgen's conduct. But Amgen's arguments ignore contrary evidence and misapply (or disregard) longstanding legal doctrines and evidentiary presumptions, which are fatal to Amgen's motion. The Court should deny Amgen's motion because Sandoz is entitled to a presumption of injury because of Amgen's conduct, the record is replete with evidence confirming Sandoz was injured, and Sandoz's expert economist has quantified those damages.

II. FACTUAL BACKGROUND

A. Amgen Develops Onpro® to Defend Against Biosimilar Competition.

Amgen launched Neulasta® in 2002. *See* Mot. at 3. For more than a decade, it enjoyed a monopoly, capturing billions of dollars in profit from its blockbuster drug. (Declaration of Todd Benoff ("Benoff Decl.") Ex. A at 4.[1]) But Amgen's last patent expired in 2015, and Amgen recognized that biosimilar competition would "have a

[1] References to the pages of exhibits to the accompanying declaration of counsel refer to the consecutive pagination of the declaration and exhibits, pursuant to L.R. 11-5.2.

material adverse impact on future sales of Neulasta®." (*Id.* at 5.) To head off the imminent biosimilar threat, Amgen launched Neulasta® Onpro®, a proprietary on-body device, which Amgen bills as "eliminat[ing] the 'next day' compliance challenges created by requiring a patient to return to the healthcare facility." Mot. at 5. But the "eliminat[ion of] the 'next day' compliance challenges" was not enough to move the market to Amgen's new device. (Benoff Decl. Ex. B at 8-9 (2018 investor reports describing that Onpro® was "generally not viewed as an important enhancement" and that there was "limited value for the convenience of OnPro.").) By this time, biosimilar competition was storming into the market. The first biosimilar pegfilgrastim launched in November 2018, and two others, including Sandoz's Ziextenzo® product, followed in 2019. (Benoff Decl. Ex. C at 80 [Delo Tr. 166:17-25].)

B. Amgen [redacted] to Defend Market Share.

Rather than competing fairly on the merits, Amgen worked to [redacted] through misleading studies that were then packaged into false and deceptive ad campaigns intended to convince healthcare providers ("HCPs") that Onpro® was safer and more effective than biosimilar pegfilgrastim products delivered via PFS. (Benoff Decl. Ex. D at 97 ([redacted]); Ex. E at 123 ([redacted]); Ex. F at 136 ([redacted]).) Based on the results of Amgen's first objectively flawed study (the "Retrospective Study"), and just months after Sandoz launched Ziextenzo®, Amgen blasted the market with advertising materials claiming that "Pegfilgrastim **PFS resulted in a significantly higher risk of FN** vs. Onpro®" and that "With PFS, **FN incidence increased by 31%** vs Onpro®." (Benoff Decl. Ex. G at 146-47; Ex. H at 157-68 [Interrog. 7].) Amgen spent [redacted] to widely distribute commercial advertisements containing these claims. (*See e.g.*, Benoff Decl. Ex. I at 173-94; Ex. J at

200-02.) And Amgen [redacted] (Benoff Decl. Ex. K at 215.)

Amgen's own documents [redacted] (Benoff Decl. Ex. L at 259.) Amgen's employees echoed those sentiments, remarking that [redacted] (Benoff Decl. Ex. M at 265; *see also* Ex. N at 268 ([redacted]).)[2]

C. [redacted], Amgen Doubles Down.

Despite Amgen's wide proliferation of "the 31% claim" and other promotional messages surrounding its studies, Amgen [redacted] (Benoff Decl. Ex. D at 97.) And it did not take long for others to catch wind of Amgen's dubious tactics. In fact, the FDA condemned Amgen's advertising in an untitled letter and rare press release, stating that Amgen's "claims and presentations create a misleading impression regarding the benefit of the" Onpro® device "by stating that there is a statistically significant higher risk of febrile neutropenia (FN) when pegfilgrastim is administered via the prefilled syringe (PFS) compared to the Onpro on-body injector (OBI)." (Benoff Decl. Ex. O at 271-75; Ex. P

[2] Tellingly, Amgen's motion mentions none of this.

at 278-79.) The FDA rebuked Amgen for its proliferation of the claims because "multiple limitations of the cited study preclude the drawing of such conclusions." (*Id.*) The FDA further lamented the advertising, noting that Amgen's "violations [we]re concerning from a public health perspective because this promotional communication's misleading claims could cause healthcare providers to conclude that Neulasta delivered via the Onpro on-body injector (OBI) is more effective than Neulasta delivered via prefilled syringe (PFS) or that it is more effective than FDA-licensed biosimilar pegfilgrastim products, which are only delivered via PFS." (*Id.*)

[redacted] (Benoff Decl. Ex. Q at 281; Ex. R at 284.) [redacted] (Benoff Decl. Ex. S at 287-94.) Amgen's Retrospective Study was never published in a peer reviewed journal. (Benoff Decl. Ex. T at 297-98 [RFA 82].) Notably, [redacted] (*See, e.g.*, Benoff Decl. Ex. U at 301-03.) But Amgen chose to [redacted] doubled down on its use of the Retrospective Study in its advertising campaigns, even after receiving the FDA's letter. (Benoff Decl. Ex. V at 305.) While Amgen claims that its "promotional materials based on the [Retrospective] study … have not been used in commercial advertising or promotion since 2021," (Dkt. 100-1 at 1-2 (Amgen's SUMF)), the evidence shows that advertisements using the 31% claim are *still currently available online* on Amgen's public-facing "Congress Hub." (Benoff Decl. Ex. W at 315-17 [Shechter Tr. 183:3-185:7]; Ex. X at 323; *see also* Ex. Y at 333-34 ([redacted]).)

But Amgen did not stop there; instead, it devised a follow-on campaign based on a second study (the "Prospective Study") that continued to perpetuate the same false narrative: that its Neulasta® Onpro® product is more effective than other pegfilgrastim PFS products, including Sandoz's Ziextenzo®. This, too, was an objectively flawed study, purporting to "prove" that Onpro® would be superior in treating FN. Again,

Amgen [redacted]. (Benoff Decl. Ex. Z at 337-38 ([redacted]); Ex. AA at 352 ([redacted]).) The resulting advertising, which claimed Onpro® resulted in "36%" and "33%" less FN was, again, false and misleading. (Benoff Decl. Ex. BB at 357.) Notably, Amgen's false advertising relying on the second study continues to this day. *See* Mot. at 19.

D. The Record is Replete with Evidence of Sandoz's Harm.

Amgen readily conceded that it [redacted] (Benoff Decl. Ex. CC at 360; Ex. DD at 363.) It is therefore unsurprising that Sandoz—the current "market leading" manufacturer of biosimilar pegfilgrastim—has suffered harm to its sales, market share, and reputation as a result of Amgen's false and misleading advertising. As set forth below, the record is replete with evidence establishing this very fact. *See infra* Section III.A.3. A leading economist has also calculated the damages Sandoz suffered because of Amgen's false and misleading campaign. (*See* Benoff Decl. Ex. EE at 410 [McDuff Rpt. ¶ 69].)

III. ARGUMENT

A. Sandoz Was Injured by Amgen's False Advertising.

Amgen's contention that it is entitled to summary judgment is wrong. Sandoz suffered injury as a direct result of Amgen's false and misleading advertising. In an attempt to evade liability, Amgen blames the victim, essentially arguing that because Sandoz encountered challenges in connection with the launch of Ziextenzo®—as is typical with any new product launch—and because [redacted] it cannot show

that it suffered any injury. But this is not the law and ignores the record.

1. The Literal Falsity of Amgen's Advertising Is a Jury Question.

Amgen concedes that the issue of literal falsity is appropriately reserved for the jury. *See, e.g.*, *Dukes v. Spence*, 2011 WL 2414514, at *1 n.1 (S.D. Cal. Feb. 4, 2011) (holding that by not moving for summary judgment on a specific issue, defendants "concede[d]" that it was "a jury question"). This concession is fatal to Amgen's motion. In false advertising cases between competitors, juries are permitted to infer that the plaintiff was injured because "literally false statements necessarily misled consumers." *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 F. App'x 609, 616 (9th Cir. 2016).[3] And because consumer deception can be presumed in literal falsity cases, "the court may grant relief without reference to the advertisement's actual impact on the buying public." *FLIR Sys. v. Sierra Media, Inc.*, 903 F. Supp. 2d 1120, 1129 (D. Or. 2012) (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 157 (2d Cir. 2007)); *see also Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1146 (9th Cir. 1997) (holding that plaintiffs were "entitled to appropriate monetary relief" based on "presumption of actual consumer deception"); *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 262 (2d Cir. 2014) (holding that "the presumption of injury" accompanying a finding of literal falsity "may be used as a basis for awarding damages in false advertising cases.").

Because Amgen tacitly concedes a jury must decide the literal falsity of its promotional materials, there necessarily remains a fact question regarding the presumption of Sandoz's injury. Summary judgment is therefore improper. *See FLIR Sys.*, 903 F. Supp. 2d at 1132 ("A domino effect occurs when there is a genuine issue of fact as to whether the advertisement is literally false. A presumption is created in the plaintiff's favor with respect [to] the remaining elements that are typically contested in Lanham Act false advertising cases, thereby precluding the grant of summary judgment

[3] As discussed below, *see infra* Section III.A.2.a, Amgen concedes—and the evidence confirms—that Sandoz and Amgen are competitors in the pegfilgrastim market.

in favor of the defendant.").[4]

2. Sandoz Is Entitled to a Presumption of Injury.

The Ninth Circuit recognizes a presumption of injury in Lanham Act cases in two additional scenarios: (1) where the plaintiff and defendant are direct competitors and the defendant's advertising tends to mislead customers; and (2) where the defendant engages in false comparative advertising. Both presumptions apply here.

a. Amgen and Sandoz are Competitors, and Amgen's Advertising is Misleading.

Sandoz is entitled to a presumption of injury because Sandoz and Amgen "are direct competitors and [Amgen's] misrepresentation[s] ha[ve] a tendency to mislead consumers." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 826 (9th Cir. 2011). The Ninth Circuit is clear: "a jury [can] infer injury based on evidence of direct competition (which provides a causal link) and a likelihood of consumer deception." *ThermoLife*, 648 F. App'x at 616; *see also Nutrition Distrib. LLC v. PEP Rsch., LLC*, 2019 WL 652391, at *5 (S.D. Cal. Feb. 15, 2019) ("When a plaintiff has shown the defendant's misrepresentation has the tendency to deceive consumers, a presumption of commercial injury may apply if defendant and plaintiff are direct competitors.").[5]

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[4] *See also Ira Green, Inc. v. J.L. Darling Corp.*, 2012 WL 4793005, at *11 (W.D. Wash. Oct. 9, 2012) (denying summary judgment on issue of damages because "there is an issue of fact on the literal falsity" of the marketing, and thus the court "cannot determine if [the plaintiff] must also show causation and damages" until it has ruled on literal falsity); *accord Fortress Secure Sols. LLC v. AlarmSIM LLC*, 2019 WL 7816820, at *9 (E.D. Wash. Dec. 5, 2019), *aff'd*, 804 F. App'x 759 (9th Cir. 2020); *Nat'l Prods. v. Gamber-Johnson LLC*, 699 F. Supp. 2d 1232, 1241 (W.D. Wash. 2010), *aff'd* 449 F. App'x 638 (9th Cir. 2011).

[5] This presumption makes sense because "[i]t is not easy to establish actual consumer deception through direct evidence," and "[t]he expenditure by a competitor of substantial funds in an effort to deceive consumers and influence their purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived." *U-Haul Int'l, Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986); *see also ThermoLife*, 648 F. App'x at 616 ("This presumption is warranted . . . because, when competitors vie for the same customers, 'a misleading ad can upset their relative

Sandoz and Amgen are direct competitors in the pegfilgrastim market. Amgen admits that it "competes with Sandoz with respect to some products, including the biosimilar to pegfilgrastim, pegfilgrastim-bmez"—*i.e.*, Ziextenzo®—and that Ziextenzo® "competes with" Amgen's Neulasta® PFS and Neulasta® Onpro products. *See* Answer (Dkt. 54) ¶¶ 130-32. Amgen's [redacted] (*See, e.g.*, Benoff Decl. Ex. FF at 519 ([redacted]).)

Additionally, Amgen's false advertising "has a tendency to mislead consumers." *TrafficSchool.com*, 653 F.3d at 826. As indicated by the FDA, Amgen's "misleading" promotional claims "could cause healthcare providers to conclude that Neulasta delivered via the Onpro on-body injector (OBI) is more effective than . . . FDA-licensed biosimilar pegfilgrastim products, which are only delivered via PFS." (Benoff Decl. Ex. O at 271.) [redacted] (Benoff Decl. Ex. GG at 522.) Amgen's second false advertising campaign—[redacted] (*see* Benoff Decl. Ex. HH at 524-25; Ex. BB at 357)—likewise has a tendency to mislead Amgen's customers. (Benoff Decl. Ex. N at 268.)

Accordingly, because the evidence establishes that Amgen and Sandoz are direct competitors in the pegfilgrastim market, and because Amgen's advertising tends to mislead customers into believing that Neulasta® Onpro® is "more effective" than

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competitive positions' and thereby cause injury."). Thus, "[h]e who has attempted to deceive should not complain when required to bear the burden of rebutting a presumption that he succeeded." *U-Haul*, 793 F.2d at 1041.

Ziextenzo®, Sandoz is entitled to a presumption of injury.

b. Amgen Engaged in False Comparative Advertising.

A presumption of injury also arises in "false comparative advertising cases, *i.e.*, where a defendant compares its product to a competing product." *W. Sugar Coop. v. Archer-Daniels-Midland Co.*, 2015 WL 12683192, at *3 (C.D. Cal. Aug. 21, 2015). In such cases, "injury can be presumed because a misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer." *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 2011 WL 4852472, at *2 (C.D. Cal. Oct. 12, 2011). Amgen acknowledges this presumption, but claims it does not apply because "Amgen's promotional materials do not 'directly compare' Neulasta® Onpro® to Ziextenzo®." Mot. at 15. Amgen is wrong. Advertisements need not "directly or explicitly compare" Neulasta® Onpro® to Ziextenzo® "to be a comparative advertisement." *U-Haul Int'l, Inc. v. Jartran, Inc.*, 601 F. Supp. 1140, 1149 (D. Ariz. 1984), *aff'd in part, rev'd in part,* 793 F.2d 1034 (9th Cir. 1986); *see also Merck Eprova AG*, 760 F.3d at 259 (rejecting assertion that "a presumption of injury is only applicable to cases of comparative advertising mentioning the plaintiff's product by name."). Rather, "[i]t is sufficient that a substantial segment of the buying public understands that the ad compares the [products] of the two competitors." *U-Haul*, 601 F. Supp at 1149.[6]

[6] In *Western Sugar*, this Court held that false advertising comparing the defendant's sugar-replacement product to "sugar" products generally created a presumption of injury in favor of the plaintiff sugar producers, even though the advertising "d[id] not involve comparisons between name-brand products." 2015 WL 12683192, at *3-4. The Court found it appropriate to apply the presumption because "the products [we]re in head-to-head competition" and the defendant's advertisements "specifically targeted and drew comparisons between its product and Plaintiffs' competing product" and made such comparisons "to stop consumers from switching from using HFCS to using sugar, and thereby stop Plaintiffs from gaining market share." *Id.*, at *16-17; *see also U-Haul Int'l, Inc. v. Jartran, Inc.*, 681 F.2d 1159, 1159-60 (9th Cir. 1982) (finding that advertisement was comparative because it "implicitly compared" the plaintiff's and defendant's products); *Time Warner*, 497 F.3d at 152 (affirming district court's

Such is the case here. Amgen's false advertising directly "compares its product"—*i.e.*, Neulasta® Onpro®—to "Pegfilgrastim PFS" and "[o]ther FN-prophylaxis options," both of which could reasonably be interpreted to compare Neulasta® Onpro® to biosimilar pegfilgrastim products, all of which—including Ziextenzo®—are delivered via PFS and are considered prophylaxis options for FN. (*See* Benoff Decl. Ex. II at 532 [Karst Rpt. ¶ 14(c)] ([redacted]); Ex. JJ at 601 [Stebel Rpt. ¶¶ 95, 98] ([redacted]).) Amgen's Senior Manager, Regulatory Affairs, testified that [redacted] (Benoff Decl. Ex. W at 311-12 [Shechter Tr. 124:15-125:5]; *see also* Ex. M at 265 [redacted]).) The FDA agreed. (Benoff Decl. Ex. O at 271, 274.)

Moreover, Amgen acknowledges that all the competing biosimilar pegfilgrastim products are only delivered via PFS. *See* Mot. at 5, 8. As the courts did in *Western Sugar*, *U-Haul*, and *Time Warner*, it is reasonable to find Amgen's customers would believe that Amgen's advertising compared its product to the biosimilar offered by [redacted] Sandoz.[7] The evidence also shows that

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determination that advertisement was comparative because, even though the advertisements "did not specifically name" the plaintiff—a leading cable company—it was sufficient that "the advertisements made explicit references to 'cable,' and . . . 'cable' is functionally synonymous with" the plaintiff's company).

[7] When Amgen began its first false advertising campaign in February 2020, there were just three competitors offering biosimilar pegfilgrastim, including Sandoz, which [redacted] (Benoff Decl. Ex. FF at 519.)

Amgen [redacted]

(Benoff Decl. Ex. CC at 360 ([redacted]); Ex. DD at 363 ([redacted]).)

Because there is evidence sufficient to support the presumption of commercial injury, Amgen's motion should be denied.[8]

[8] Amgen contends that "Courts have routinely rejected a presumption of injury for similar promotions." Mot. at 15 & n.8. But the cases Amgen cites for that proposition are inapposite. In *Pom Wonderful*, the defendant's advertising broadly compared its product to "other drinks, including red wine, green tea, blueberry juice and cranberry juice cocktail," which the court determined was too "generic" to be viewed as making a comparison to any specific product. 2011 WL 4852472, at *3; *see also CKE Rest. v. Jack in the Box, Inc*., 494 F. Supp. 2d 1139, 1145 (C.D. Cal. 2007) (finding no "direct comparison" where the advertisement merely referred generically to "our competitor's product"); *Munchkin, Inc. v. Playtex Prods., LLC*, 2012 WL 12886205, at *2 (C.D. Cal. Oct. 4, 2012) (finding that advertisement was not comparative where defendant's merely stated that their products were "Proven #1" and "#1 Recommended" without any explicit or implicit reference to competitors). In *Out of the Box Enters., LLC v. El Paseo Jewelry Exch., Inc.*, 2012 WL 12893690, at *13 (C.D. Cal. May 11, 2012), the advertisement made no comparison to a competitor's product at all, but rather simply made "a barb directed at" its competitor. *Id*., at *13. Amgen's reliance on *Falcon Stainless, Inc. v. Rino Companies, Inc*., 2011 WL 13130703 (C.D. Cal. Oct. 21, 2011), is also misplaced, as that case dealt with the propriety of a "presumptive damages award" equal to the amount that the defendant spent on the false advertising, not a presumption of injury at the summary judgment stage. *Id*., at *14-15; *cf. Harper House, Inc. v. Thomas Nelson, Inc*., 889 F.2d 197, 209 (9th Cir. 1989) ("The presumption of damages in the amount defendants spent on advertising is not, however, a presumption of the fact of injury."). In any event, and to avoid the overcompensation concerns underlying the court's decision in *Falcon Stainless*, Sandoz explicitly accounted for the

3. Even Without a Presumption of Commercial Injury, There Is Evidence Sandoz Was Injured.

Even if this Court finds that Sandoz is not entitled to a presumption of injury—or, alternatively, that Amgen has rebutted that presumption—the Court should nevertheless deny Amgen's motion because there is evidence Sandoz was injured.

a. Sandoz Lost Sales Due to Amgen's False Advertising.

Amgen contends that Sandoz cannot show any injury because there is "no evidence" that Sandoz "lost any sales" as a result of Amgen's false advertising. Mot. at 10-15. But in making this argument, Amgen fails to acknowledge record evidence and wholly ignores Sandoz's expert economist's report that calculated Sandoz's damages arising out of the false advertising.[9] In his report, Dr. DeForest McDuff analyzed market and sales data to determine the extent of the impact of Amgen's false advertising on Sandoz's sales and concluded that Amgen's false advertising caused Sandoz to lose more than [redacted] in net profits to Amgen. (Benoff Decl. Ex. EE at 410 [McDuff Rpt. ¶ 69].) In calculating damages, Dr. McDuff considered the other issues that impacted Sandoz's sales during the relevant time period, including the COVID-19 pandemic. (*Id*. [¶¶ 55, 73–85].) Dr. McDuff's damages report provides a reasonable basis upon which the jury could determine both the fact and amount of Sandoz's lost sales to Amgen. "As a general rule, summary judgment is inappropriate where an expert's testimony supports the nonmoving party's case," and thus the Court should deny Amgen's motion. *Southland Sod Farms*, 108 F.3d at 1144, 1146 (holding that plaintiffs' damages expert report "provides adequate evidence for a reasonable jury to conclude that Plaintiffs suffered actual injury as a result of Defendants'

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presence of other biosimilar pegfilgrastim manufacturers in the market in calculating its damages in this case. (Benoff Decl. Ex. EE at 409-10 [McDuff Rpt. ¶¶ 68-69].)

[9] It is axiomatic that Amgen "cannot prevail on a motion for summary judgment by simply ignoring large swaths of evidence." *In re Roundup Prods. Liab. Litig.*, 364 F. Supp. 3d 1085, 1089 (N.D. Cal. 2019), *aff'd*, 997 F.3d 941 (9th Cir. 2021).

advertisements.") (citation omitted); *see also, e.g.*, *Trekeight, LLC v. Symantec Corp.*, 2006 U.S. Dist. LEXIS 100609, at *27-28 (S.D. Cal. May 23, 2006) (holding that plaintiff's expert report was sufficient to create "a triable issue of material fact as to [the injury] element of Plaintiff's Lanham Act claim").

Even so, "direct evidence of lost sales or concrete proof of injury" is not required, *Santos Electronics Inc. v. Outlaw Audio, LLC*, 2022 WL 18396275, at *8 (C.D. Cal. Dec. 12, 2022) (citation omitted), and "[a] plaintiff who can't produce lost sales data may . . . establish an injury by creating a chain of inferences showing how defendant's false advertising could harm plaintiff's business," *TrafficSchool.com*, 653 F.3d at 825.[10] To make this showing, the Lanham Act "demands neither empirical quantification nor expert testimony." *Skydive Ariz., Inc. v. Quattrocchi*, 673 F.3d 1105, 1113 (9th Cir. 2012). Rather, "many sources can provide the requisite information upon which a reasonable jury may calculate damages." *Id.*

Here, there is ample evidence through which a reasonable jury could infer that Amgen's false advertising caused Sandoz to lose sales.[11] For example, [redacted]

[redacted]

[redacted]

[10] This malleable approach to proving injury "makes sense, because proving a counterfactual is never easy, and is especially difficult when the injury consists of lost sales that are predicated on the independent decisions of third parties; *i.e.*, customers." *TrafficSchool.com*, 653 F.3d at 825.

[11] Notably, Amgen's current lead counsel recently made this very argument in a similar case before this Court. In *Allergan USA, Inc. v. Imprimis Pharmaceuticals, Inc.*, No. 8:17-cv-01551-DOC-JDE (C.D. Cal. July 8, 2019), Defendant's counsel argued that calculating lost sales attributable to false advertising is "an imprecise task assigned to the trier of fact." *Id.*, Dkt. 257 at 20. Accordingly, counsel argued, because *"[t]here is no practical way to objectively prove which of [defendant's] hundreds of thousands of individual sales were caused by false advertising, and which were not*," juries are "routinely" entrusted to "take into account all the evidence, direct and circumstantial alike, and bring their experience and wisdom to bear to arrive at an answer." *Id.* (emphasis added).

[redacted] *See* (Benoff Decl. Ex. KK at 746, 771-72.) In fact, Amgen's [redacted] (*Id*. at 746, 772.) [redacted] (*Id*.) [redacted] sufficient to, at a minimum, create a triable jury question regarding whether Amgen's false advertising injured Sandoz by influencing providers to prescribe Neulasta® Onpro over competing pegfilgrastim products, including Ziextenzo®.[12]

Furthermore, [redacted] (*See, e.g.*, Benoff Decl. Ex. NN at 907-08 ([redacted]); Ex. N at 268 ([redacted]).) Amgen also acknowledges that Ziextenzo® is "the market leading Neulasta® biosimilar by volume," *see* Mot. at 8, and because each sale of Neulasta® Onpro® logically comes at the expense of another pegfilgrastim product, it

[12] Sandoz also produced an expert report from Dr. Matthew Perri, who analyzed Amgen's advertising campaigns and concluded that they [redacted] (Benoff Decl. Ex. LL at 837 [Perri Rpt. ¶ 98].) Additionally, [redacted] (Benoff Decl. Ex. MM at 897.)

follows that at least some of these sales would have otherwise gone to Sandoz.[13] *See TrafficSchool.com*, 653 F.3d at 825 (holding that because the parties compete for the same revenue, "[s]ales gained by one are thus likely to come at the other's expense."). Viewed in the light most favorable to Sandoz, this evidence plausibly "create[es] a chain of inferences showing how [Amgen's] false advertising could harm [Sandoz's] business," which is all that is required. *Id.*[14]

b. Sandoz's Injuries Are Not Limited to Lost Sales.

Amgen's argument also fails because it is based on the faulty premise that the *only* injury Sandoz could have suffered is in the form of lost sales. Mot. at 11-15. But neither the case law nor the evidence supports Amgen's narrow interpretation of the injury element of Sandoz's Lanham Act claim.

For example, Sandoz can establish a commercial injury by showing that it lost

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[13] Amgen argues that in a multiplayer market, no presumptions of injury apply. But such a holding would read the Lanham Act a dead letter when there are multiple competitors, providing companies with a license to deceive because they face competition from multiple players. That is wrong as a matter of both logic and law. Rather, for the presumption of injury to apply, it is sufficient that Sandoz and Amgen are "direct competitors" who "vie for the same customers." *ThermoLife*, 648 F. App'x at 615-16.

[14] Amgen also argues that Sandoz's lost sales were the result of "other business factors unrelated to Amgen's promotional materials," and contends that Sandoz "has failed meaningfully to account for these factors or exclude them as causes of its alleged damages." Mot. at 14 & n.7. Here again, Amgen's argument ignores the fact that Sandoz's damages expert expressly *did* account for these other factors in modeling the portion of Sandoz's lost sales specifically attributable to Amgen's false advertising. (*See* Benoff Decl. Ex. EE at 401-02, 413-26 [McDuff Rpt. ¶¶ 55, 73–85].) In any event, Sandoz is not required to show that Amgen's false advertising was the sole cause of its losses, but rather only that it was a "substantial factor in causing pecuniary loss." *U-Haul*, 601 F. Supp. at 1150; *see also Allergan USA, Inc. v. Imprimis Pharms., Inc.*, 2019 WL 4546897, at *5 (C.D. Cal. Aug. 2, 2019) (holding that the existence of "other factors affecting the market . . . does not mean that the jury could not infer any connection between lost sales and false advertisements."); *Scilex Pharms. Inc. v. Sanofi-Aventis U.S. LLC*, 552 F. Supp. 3d 901, 912 (N.D. Cal. 2021) (rejecting as "unavailing" defendant's argument that the existence of "other market forces" prevents the plaintiff from proving that it was harmed by defendant's false advertising).

market share due to Amgen's false advertising, or that Amgen's actions prevented Sandoz from entering the market or expanding its market share in the first place. *See Obesity Rsch. Inst., LLC v. Fiber Rsch. Int'l, LLC*, 310 F. Supp. 3d 1089, 1127 (S.D. Cal. 2018) (denying summary judgment on issue of injury because plaintiffs provided evidence that they "sought to expand into the glucomannan supplement market, but were shut out of the market by [defendant] and its advertising."). The record in this case shows that [redacted] (*Compare* Benoff Decl. Ex. OO at 912, *with* Ex. PP at 916.) The evidence also reflects that [redacted] (Benoff Decl. Ex. QQ at 918; Ex. RR at 921; *see also* Ex. SS at 925 ([redacted]).) There is thus ample evidence from which a reasonable jury could determine that Amgen's advertising stunted Sandoz's entry into the pegfilgrastim market and ultimately prevented Sandoz from obtaining a larger market share.

The record also shows that Sandoz [redacted] *See* (Benoff Decl. Ex. TT at 935-54 [Interrog. 7].) This, too, is an actionable injury under the Lanham Act. *Certified Nutraceuticals, Inc. v. Clorox Co.*, 2021 WL 4460806, at *7 & n.1 (S.D. Cal. Sept. 29, 2021) (permitting plaintiff to prove Lanham Act injury through past corrective advertising costs, but finding that plaintiff failed to sufficiently tie those costs to defendant's false advertising); *U-Haul*, 793 F.2d at 1041 (acknowledging "the propriety of basing a damage award on corrective advertising expenditures.").

Finally, while Amgen baldly asserts that "Sandoz has no evidence of reputational harm," Mot. at 11 n.5, the record in this case contains plenty of evidence [redacted] (*See, e.g.*, Benoff Decl. Ex. UU at 958 ([redacted]); Ex. VV at 961 ([redacted]).) Because reputational harm is an actionable injury under the Lanham Act, Amgen's Motion should be denied. *Trovan, Ltd. v. Pfizer, Inc.*, 2000 WL 709149, at *12 (C.D. Cal. May 24, 2000) (holding that the jury can infer injury due to reputational harm, which is a "sufficient injury to warrant an award of damages").

4. Sandoz Is Entitled to Disgorgement of Amgen's Profits.

Amgen also argues that Sandoz is not entitled to disgorgement of Amgen's profits because Sandoz "fail[ed] to prove injury"[15] and this case does not fall within the "limited circumstances" in which courts award disgorgement of profits without proof of harm. Mot. at 16-17. But for all the reasons discussed above, there is ample evidence from which a reasonable jury could determine that Sandoz was injured by Amgen's false and misleading advertising. Moreover, the *Grasshopper House, LLC v. Clean & Sober Media, LLC*, 2021 WL 3702243 (9th Cir. Aug. 20, 2021) case cited by Amgen undermines Amgen's disgorgement argument because there, the Ninth Circuit held that it was error to deny plaintiff's request for disgorgement of profits despite finding that

[15] Here again, Amgen's current lead counsel previously advocated for the exact opposite outcome on this issue, arguing to this Court that a plaintiff's "inability to show actual damages does not alone preclude a recovery under section 1117," and that "even if [plaintiff] had not proven its own damages, it could still recover [defendant's] profits." *See Allergan*, No. 8:17-cv-01551-DOC-JDE (C.D. Cal. Feb. 4, 2019), Dkt. 116 at 12 n.7 (citing *Southland Sod*, 108 F.3d at 1146; 15 U.S.C. § 1117(a)).

there was insufficient evidence of lost profit damages. *Id.*, at *1-4. Further, disgorgement of profits is appropriate where it is necessary to deter the defendant from engaging in false advertising by "tak[ing] all the economic incentive out of" the conduct. *Playboy Enters., Inc. v. Baccarat Clothing Co.*, 692 F.2d 1272, 1275 (9th Cir. 1982); *see also TrafficSchool.com*, 653 F.3d at 831 ("[A]n award of profits with no proof of harm . . . [is] appropriate where ordinary damages won't deter unlawful conduct."). And the policy justifications underlying deterrence-based disgorgement are equally compelling if a jury was unable to quantify the damage Sandoz suffered as a result of Amgen's misdeeds. *See Monster Energy Co. v. Integrated Supply Network, LLC*, 533 F. Supp. 3d 928, 933 (C.D. Cal. 2021) (holding that "disgorgement of profits would assist in deterring Defendant from continuing to infringe on Plaintiff's trademarks, particularly since the jury awarded $0 in compensatory damages."). As such, the Court could nevertheless exercise its equitable authority to award Sandoz a sum equal to Amgen's profits from the false and misleading advertising to deter Amgen from engaging in such conduct in the future. *See* 15 U.S.C. § 1117(a).[16]

B. Sandoz Is Entitled to Injunctive Relief.

In addition to seeking monetary relief, Sandoz also seeks various forms of injunctive relief under its Lanham Act, UCL, and FAL claims, including injunctions prohibiting Amgen from continuing to engage in false and misleading advertising and requiring Amgen to engage in corrective advertising. *See* Compl. (Dkt. 1) ¶¶ 146, 154, 161 & Prayer for Relief ¶¶ C-D. Amgen moves for summary judgment on these claims based solely on its contention that Sandoz "cannot show that it faces a likelihood of future injury." Mot. at 18. Amgen again misses the mark.

First, with respect to Amgen's Retrospective Study (*i.e.*, the first campaign),

[16] [redacted] (Benoff Decl. Ex. EE at 410-12, 427-28 [McDuff Rpt. ¶¶ 70-71, 90].)

Amgen contends that injunctive relief is unnecessary because "Sandoz has no evidence Amgen will ever use that promotion again." *Id*. But it is not Sandoz's burden to prove that Amgen will not use the advertising again. Instead, "[w]hen a defendant claims injunctive relief is unwarranted, the defendant bears the formidable burden of demonstrating voluntary compliance by showing it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Monster Energy Co. v. Vital Pharms., Inc.*, 2023 WL 2918724, at *5 (C.D. Cal. Apr. 12, 2023). Amgen has made no such showing. To the contrary, the evidence shows that advertisements using the 31% claim are *still currently available online* on Amgen's public-facing "Congress Hub." (Benoff Decl. Ex. W at 315-17 [Shechter Tr. 183:3-185:7]; Ex. X at 323.) Moreover, Amgen's documents make clear that even after the FDA's admonishment, Amgen [redacted] (Benoff Decl. Ex. Y at 333-34.) Sandoz is entitled to injunctive relief because Amgen has not met—and cannot meet—its "formidable burden" of proving that there is no risk of continued false advertising.

Amgen also argues that injunctive relief is unwarranted with respect to its Prospective Study (*i.e.*, the second campaign) because there is "no evidence" that these promotional materials are likely to harm Sandoz in the future. Mot. at 19. Once again, this is belied by the evidence, including the fact that the second campaign is both misleading and continues to be deployed by Amgen's sales team. *See supra* Section II.C. at 4-5; (Benoff Decl. Ex. N at 268.). In any event, the law is clear that "a competitor need not prove injury when suing to enjoin conduct that violates section 43(a)." *Quidel Corp. v. Siemens Med. Sols. USA, Inc*., 2021 WL 4622504, at *3 n.6 (9th Cir. Oct. 7, 2021). Because a reasonable jury could find that Amgen's second campaign is both ongoing and false and misleading, summary judgment is improper.

Finally, Amgen glosses over the fact that Sandoz also seeks injunctive relief in the form of corrective advertising. Injunctive relief is proper because "courts have long ordered defendants to engage in corrective advertising campaigns following their

infliction of Lanham Act injuries." *Merck Eprova AG v. Gnosis S.p.A.*, 2013 U.S. Dist. LEXIS 49798, at *6 (S.D.N.Y. Mar. 7, 2013), *aff'd*, 760 F.3d 247 (2d Cir. 2014); *see also*, *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 479 (D.N.J. 2009) ("Corrective advertising is appropriate when, as here, a defendant is making false claims about its product that bear on the public health."). The record is replete with evidence of customers being misled by Amgen's false advertising, *see supra* Section III.A.3.a, and Sandoz's experts have opined that Amgen's advertising [redacted] (Benoff Decl. Ex. EE at 398-400 [McDuff Rpt. ¶¶ 47, 49].) Sandoz is therefore entitled to corrective advertising "to remedy consumer confusion caused by false advertising messages," and the Court should deny Amgen's motion. *Healthport Corp. v. Tanita Corp. of Am.*, 563 F. Supp. 2d 1169, 1182 (D. Or. 2008).

IV. CONCLUSION

For the foregoing reasons, Amgen's motion should be denied.

Dated: June 5, 2023

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LOCAL RULE 11-6.2 CERTIFICATE OF COMPLIANCE

The undersigned, counsel of record for Sandoz Inc., certifies that this brief contains 6,989 words, which complies with the word limit of L.R. 11-6.1.

Dated: June 5, 2023

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